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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,276	11/30/2006	Wenyan Wu	3278-7887US	2424

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EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	PAPER NUMBER
1652	

NOTIFICATION DATE	DELIVERY MODE
01/08/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary	Application No.	Applicant(s)	
	10/585,276	WU, WENYAN	
	Examiner	Art Unit	
	CHRISTIAN L. FRONDA	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *6,7 and 12-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 8-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/28/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-17 are pending in the instant Office Action.

2. Applicants' election without traverse of Invention I (claims 1-5 and 8-11) in the reply filed on 09/14/2009 is acknowledged. Claims 6, 7, and 12-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. The requirement is deemed proper and is therefore made FINAL.

3. Claims 1-5 and 8-11 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 2-5, 9-11 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

The claims, as written, do not sufficiently distinguish over peptides as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated peptide" or "Purified peptide ". See MPEP 2105.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-5 and 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9-11 as written depend from claims 2-4, respectively. However, claims 2-4 as written depend from claim 8. The claims are vague and indefinite because it is unclear as to what claims are independent claims and what specific claims are the dependent claims. Appropriate correction is requested.

The claims recite the phrase "active principles of natural musk" which renders the claims vague and indefinite because the meaning of the phrase is not known and it is unclear what substances are encompassed by "active principles of natural musk". For examination purposes the claims are interpreted as not being limited to "active principles of natural musk"

Claim Rejections - 35 U.S.C. § 112, First Paragraph

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 2-5, 9-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated peptide comprising SEQ ID NO: 1, 2, 3, 4, or 5; **does not** reasonably provide enablement for any isolated peptide comprising SEQ ID NO: 5 where the sequence of the peptide is at least 30% conserved with SEQ ID NO: 1, 2, 3, or 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is

most nearly connected, to make and/or use the invention commensurate in scope with these claims.

According to MPEP 2164.01(a), factors considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. MPEP§ 2164.04 states that while the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection. The language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. Accordingly, the factors most relevant to the instant rejection are addressed in detail below.

The nature and breadth of the claims encompass any isolated peptide comprising SEQ ID NO: 5 where the sequence of the peptide is at least 30% conserved with SEQ ID NO: 1, 2, 3, or 4. The reference of Chica et al. (Curr Opin Biotechnol. 2005 Aug;16(4):378-84; PTO 892) teaches that the complexity of the structure/function relationship in enzymes has proven to be the factor limiting the general application of rational enzyme modification and design, where rational enzyme modification and design requires in-depth understanding of structure/function relationships. The reference of Sen et al. (Appl Biochem Biotechnol. 2007 Dec;143(3):212-23; PTO 892) teaches *in vitro* recombination techniques such as DNA shuffling, staggered extension process (StEP), random chimeragenesis on transient templates (RACHITT), iterative truncation for the creation of hybrid enzymes (ITCHY), recombined extension on truncated templates (RETT), and so on have been developed to mimic and accelerate nature's recombination strategy. However, such rational design and directed evolution techniques only provide guidance for searching and screening for the claimed invention.

The specification provides guidance, prediction, and working examples for an isolated peptide comprising SEQ ID NO: 1, 2, 3, 4, or 5. However, the specification does not provide guidance, prediction, and working examples for making and/or using the invention as claimed.

The specification and art do not provide a correlation between any structure and biological function of the peptides other than an isolated an isolated peptide comprising SEQ ID NO: 1, 2, 3, 4, or 5 based on which those of ordinary skill in the art could predict which amino acids can vary from SEQ ID NO: 1, 2, 3, 4, or 5 without losing its biological activity. Consequently, there is no information about which amino acids can vary from SEQ ID NO: 1, 2, 3, 4, or 5 and still retain its biological activity.

Thus, one must perform an enormous amount of trial and error experimentation to search and screen for any isolated peptide comprising SEQ ID NO: 5 where the sequence of the peptide is at least 30% conserved with SEQ ID NO: 1, 2, 3, or 4 from any biological source or make mutations including amino acid substitutions, additions, deletions, and combinations thereof to the peptide to make a peptide comprising SEQ ID NO: 5 where the sequence of the peptide is at least 30% conserved with SEQ ID NO: 1, 2, 3, or 4, and determining whether the peptide still retains its biological activity. Furthermore, one must perform an enormous amount of trial and error experimentation to search and screen the specific biological functions of any isolated peptide comprising SEQ ID NO: 5 where the sequence of the peptide is at least 30% conserved with SEQ ID NO: 1, 2, 3, or 4. General teaching regarding screening and searching for the claimed invention using activity assays stated in the specification is not guidance for making the claimed invention.

Therefore, in view of the overly broad scope of the claims, the specification's lack of specific guidance and prediction, the specification's lack of additional working examples, and the amount of experimentation required; it would require undue experimentation for a skilled artisan to make and use the claimed invention. Without sufficient guidance, the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988).

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Accession Q7X1D7 (published 01-OCT-2003; PTO 892)

Accession Q7X1D7 teaches a peptide comprising SEQ ID NO: 5 (see attached alignment). Thus, the reference teachings anticipate the claimed invention.

12. Claims 1-5 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu et al. (ACTA Zoologica Simica, September 1992, pp. 302-308, Vol 38, No. 3; from IDS filed 12/28/2006).

Liu et al. teach an anti-inflammatory peptide isolated from musk which suggests a minimum protein of 374 amino acids comprising acidic (Glu, Asp) and basic (arg, His) amino acid residues having its isoelectric point of about pH 3-4 (see abstract). Since the source of the reference peptide and the claimed peptide are one and the same, which is musk, the examiner takes the position that the peptide taught by Liu et al. would inherently have the amino acid sequences recited in the claims. Therefore, the teachings of Liu et al.. anticipate claims as written.

Since the Patent Office does not have the facilities for examining and comparing the peptide of the claims to the peptide taught by Liu et al., the burden is on applicant to show that the prior art peptide is different from the claimed peptide. See *In re Best*, 562 F.2d 1252, 195 USPQ 430(CCPA 1977).

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Thursday and alternate Fridays between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christian L. Fronda/
Primary Examiner
Art Unit 1652